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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	10/607,809
		Filing Date	June 27, 2003
		First Named Inventor	Leonard KATZ
		Art Unit	1632
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	6	Attorney Docket Number	300622004810

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (3 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form PTO-1449 (2 pages) Return Receipt Postcard
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	MORRISON & FOERSTER LLP Brenda J. Wallach - 45,193
Signature	<i>Brenda J. Wallach</i>
Date	December <u>11</u> , 2003

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.	
Dated: December <u>11</u> , 2003	Signature: <i>Diane Blevins</i> (Diane Blevins)



PATENT  
Docket No. 300622004810

**CERTIFICATE OF MAILING BY "FIRST CLASS"**

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Diane Blevins

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the application of:

Leonard KATZ, *et al.*

Serial No.: 10/607,809

Filing Date: June 27, 2003

For: PRODUCTION OF POLYKETIDES

Examiner: Unassigned

Group Art Unit: 1632

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action directed to the related application Serial Number 09/697,022 filed 25 October 2000, which issued on 30 September 2003 as U.S. Patent No. 6,627,427. Accordingly, copies of these documents are not included herewith. This protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

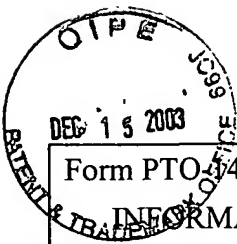
The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 300622004810 However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 11, 2003

Respectfully submitted,

By: Brenda J. Wallach  
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Form PTO/SB/08 (2-92)

Docket Number 300622004810

Application Number 10/607,809

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Applicant

Leonard KATZ et al.

Filing Date June 27, 2003

Group Art Unit 1632

Mailing Date: December 11, 2003

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	05/1997	5,672,491	Khosla et al.	435	148	
	2.	10/1999	5,962,290	Khosla et al.	435	183	
	3.	03/2000	6,033,883	Barr et al.	435	148	
	4.	05/2000	6,066,721	Khosla et al.	536	23.1	
	5.	06/2000	6,080,555	Khosla et al.	435	41	
	6.	07/2001	6,262,340	Betlach et al.	800	278	
	7.	10/2001	6,303,342	Julien et al.	435	76	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	NO
	8.	04/1997	WO 97/13845	PCT				
	9.	11/1998	WO 98/49315	PCT				
	10.	01/1999	WO 99/02669	PCT				
	11.	01/1999	WO 99/03986	PCT				
	12.	04/2001	WO 01/27306	PCT				
	13.	05/2001	WO 01/31035	PCT				

## OTHER DOCUMENTS

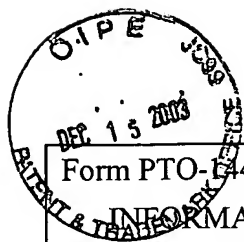
(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	14.	Donadio et al. "Erythromycin Production in Saccharopolyspora Erythraea Does Not Require a Functional Propionyl-CoA Carboxylase" Molecular Microbiology (1996) 19(5):977-984.
	15.	Gokhale et al. "Dissecting and Exploiting Intermodular Communication in Polyketide Synthases" Science (1999) 284:482-485.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.



Form PTO-1449

Docket Number 300622004810

Application Number 10/607,809

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Applicant

Leonard KATZ et al.

Filing Date June 27, 2003

Group Art Unit 1632

Mailing Date: December 11, 2003

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| 16. | Hsieh and Kolattukudy "Inhibition of Erythromycin Synthesis by Disruption of Malonyl-Coenzyme A Decarboxylase Gene <i>eryM</i> in <i>Saccharopolyspora erythraea</i> " J. Bact. (1994) 176(3):714-724.   |
| 17. | Kao et al. "Engineered Biosynthesis of a Complete Macrolactone in a Heterologous Host" Science (1994) 265:509-512.   |
| 18. | Kealey et al. "Production of a Polyketide Natural Product in a Nonpolyketide-Producing Prokaryotic and Eukaryotic Hosts" PNAS (1998) 95:505-509.   |
| 19. | Khosla et al. "Tolerance and Specificity of Polyketide Synthases" Annual Review of Biochemistry (1999) 68:219-253.   |
| 20. | Kuhstoss et al. "Production of a Novel Polyketide Through the Construction of a Hybrid Polyketide Synthase" Gene (1996) 183(1):231-236.  |
| 21. | Liu et al. "Precursor Supply for Polyketide Biosynthesis: The Role of Crotonyl-CoA Reductase" Metabolic Engineering (2001) 3(1):41-48.   |
| 22. | Pfeifer et al. "Biosynthesis of Polyketides in Heterologous Hosts" Microbiology and Molecular Biology Reviews (2001) 65(1):106-118.  |
| 23. | Pieper et al. "Erythromycin Biosynthesis: Kinetic Studies on a Fully Active Modular Polyketide Synthase Using Natural and Unnatural Substrates" Biochemistry (1996) 35(7):2054-2060.   |
| 24. | Stassi et al. "Ethyl-Substituted Erythromycin Derivatives Produced by Directed Metabolic Engineering" PNAS (USA) (1998) 95(13):7305-7309.  |
| 25. | Tang et al. "Amino Acid Catabolism and Antibiotic Synthesis: Valine is a Source of Precursors for Macrolide Biosynthesis in <i>Streptomyces Ambofaciens</i> and <i>Streptomyces Fradiae</i> " J. of Bacteriology (1994) 176(19):6107-6119.             |
| 26. | Tuchman et al. "Enhanced Production of Arginine and Urea by Genetically Engineered <i>Escherichia Coli</i> K-12 Strains" Applied and Environmental Microbiology (1997) 63(1):33-38.  |
| 27. | Vrijbloed et al. "Insertional Inactivation of Methylmalonyl Coenzyme (CoA) Mutase and Isobutyryl-CoA Mutase Genes in <i>Streptomyces Cinnamomensis</i> : Influence on Polyketide Antibiotic Biosynthesis" J. of Bacteriology (1999) 181(18):5600-5605. |
| 28. | Wallace et al. "Purification of Crotonyl-CoA Reductase from <i>Streptomyces Collinus</i> and Cloning, Sequencing and Expression of the Corresponding Gene in <i>Escherichia Coli</i> " European J. of Biochemistry (1995) 233(3):954-962.              |
| 29. | Wawskiewicz et al. "Propionyl-CoA* Dependent H <sup>14</sup> CO <sub>3</sub> -Exchange into Methylmalonyl-CoA in Extracts of <i>Streptomyces Erythraeus</i> " Biochemische Zeitschrift (1964) 340:213-227.   |
| 30. | Xue et al. "A Multiplasmid Approach to Preparing Large Libraries of Polyketides" PNAS (USA) 96(21):11740-11745.  |
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